IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Terrence R. Langford	DOCKET NO.:	122123.00004US1
SERIAL NO.:	10/552,879	EXAMINER:	Delcotto, Gregory R.
FILED:	10/12/2005	ART UNIT:	1751

CONFIRMATION NO.: 4467

TITLE: SUPPLEMENTAL OZONE TREATMENT METHODS FOR DIFFICULT CLEANING AND STERILIZING APPLICATIONS

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Gavin J. Milczarek-Desai Quarles & Brady LLP One South Church Ave., Suite 1700 Tucson, AZ 85701

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that on this 15th day of March, 2007, this correspondence is being transmitted via EFS-WEB to the United States Patent and Trademark Office, Patent Technology Center 1700, Art Unit 1751.

By: Alice B. Vanicek
Alice B. Vanicek

TO THE COMMISSIONER FOR PATENTS

DECLARATION BY TERRENCE R. LANGFORD

I, Terrence R. Langford, hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that I have full knowledge and understanding of the fact that willful false statements and the like made herein are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that any such statements may jeopardize the validity of the above-referenced application or of any patent granted on it.

1. I am a graduate of the University of Witwatersrand in South Africa, where I received a Bachelors of Commerce in 1975 and an MBA in 1979.

2. In addition to my formal education, I have over 30 years of experience working in fields relating to the mechanical arts, including seven years as a mechanical service analyst for a dealership of the Caterpillar Corporation and over fifteen years of experience in the design, development, and testing of devices that clean, disinfect, and/or sterilize medical items and instruments. I also am the President and CEO of the company Langford IC Systems, Inc., which has developed and obtained FDA premarket approval for a cleaner/processor device for reprocessing medical items and instruments.

3. As a result of my technical and work experience, I have a thorough understanding of the history and the current state of the art of products in, as well as the mechanical and biological principals underlying, the field of instrument cleaning and disinfecting.

4. I have read and understood U.S. Patent Application Serial No. 10/552,879 covering the cleaning and disinfecting methods of the present invention.

5. I also have read the Office Action from the Patent Office dated November 1, 2006, the Guess reference (WO02/32467), the Langford reference (U.S. Patent 5,443,801; hereinafter the '801 patent) and the Hitchems et al. reference (U.S. Patent 6,468,953) cited by the Examiner.

6. I also have read and understood the rejections made under 35 U.S.C. 112 found on page 3 of the Office Action.

7. Based on my professional knowledge and experience, the term "high-level disinfection" was known to one skilled in the art at the time that the invention of U.S. Patent Application Serial No. 10/552,879 was made as disinfection that kills all organisms except high levels of bacterial spores. This definition is supported by Exhibits 1 and 2 provided herewith.

8. I also understand the Examiner's position regarding the rejection of the claims under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) as expressed starting on page 5 and continuing through page 8 of the Office Action.

9. Based on my professional knowledge and experience, the invention is new and different from the Guess reference because the Guess reference does not disclose or suggest the claimed contamination-prevention method steps, which occur after high-level disinfection. Moreover, there is no disclosure in Guess that is directed to rinsing components of a disinfecting apparatus with water and ozone after an item has been high-level disinfected. Attached to this Declaration is Exhibit 3 (see especially ¶3 on page 1 and page 4, ¶7 through page 5, ¶3), which attests to the continuing need to provide a post-disinfection rinse that does not result in re-contamination.

10. Based on my professional knowledge and experience, the invention is unobvious in view of the '801 patent and Hitchems et al. references because neither of these disclose, alone or in combination, a method as recited in claim 14. In particular, I note that the '801 patent's use of

ozonated water in repeated rinse cycles is disclosed to effect sterilization rather than to provide a final chemical-degrading and biomatter "overkill" rinse of an already high-level disinfected item with water and then ozone as recited in claim 14. Moreover, I believe that one of ordinary skill in the art would not take the '801 patent's repeated rinsing with ozonated water to suggest a separate chemical degradation and biomatter "overkill" rinse because no chemical sterilant is used in the '801 patent's disclosed method.

11. I also believe that the invention is not obvious because the claimed method has produced unexpected results. Indeed, the claimed methods are so unexpectedly effective (> 6 log reduction of microbial loading with no colony forming units (CFU's) and < 6.4 ug/cm^2 protein remaining after cleaning) that the FDA now defines the high-level disinfecting standards used for testing washer/disinfector devices as the "Langford IC Systems (LIC) Requirements" as shown in Exhibit 4 at page 3, ¶5.3.

12. In addition, I believe there has been and continues to be long-felt need in the medical instrument reprocessing industry for a method that provides a final chemical-degrading and biomatter "overkill" rinse of an already high-level disinfected item with water and ozone. This belief is based on my experience in the field and reports such as that attached to this Declaration as Exhibit 3.

13. As further attestation of non-obviousness, there also has been a failure of others to provide the degree of cleaning and high-level disinfection achieved by the claimed methods. For example, the FDA recently has created a new category of reprocessor device known as a "cleaner/processor." The cleaning and disinfection standard associated with this category is based on our test results and includes the following requirements: A single chamber device should be capable of cleaning an instrument to a residue level of < 6.4 μg/cm^2 of protein from a bio burden of at least 300 μg/cm^2 of protein, achieve the high-level disinfection of an instrument contaminated with horse serum and 7 logs of *Mycobacterium terrae* to a SAL of >6 with no surviving CFU's, have an integrated rinse water system capable of producing a sanitized rinse water from water contaminated with 7 logs of *Staphylococcus aureus, Bacillus subtilis, Pseudomonas aeruginosa and Candida albicans*, and be able to rinse off germicide residue without compromising the integrity of the high-level disinfection process. As the methods of the invention are responsible for setting this new standard, others have failed to achieve same.

14. I also believe the invention is not obvious because, while many medical instruments today are routinely cleaned, disinfected, and reused, experts in the field have warned that some of the more difficult to clean and sterilize medical items can remain contaminated. Hence, there has been a skepticism in the field generally regarding the ability of washer/disinfection devices to reliably produce contamination-free performance (see Exhibit 5).

15. Accordingly, it is my conclusion that the cited references would not anticipate or render obvious the present invention because there is no disclosure or suggestion of the recited method steps, which, in combination with the unexpected results, long felt need, failure of others, and skepticism of experts described above, demonstrate that the invention is novel and

inventive over the prior art.

Respectfully submitted,

By: _____
Terrence R. Langford, President and CEO

Dated: 3/14/07